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WRIGHT MEDICAL TECHNOLOGY
A Wright Medical Group Company

AUG 19 2011

510(k) Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® E Cementless Hip Stem.

(a)(1) Submitted By

Submitter's Name:

Wright Medical Technology, Inc.
5677 Airline Rd. Arlington, TN 38002
800-238-7188 (phone), 901-867-4190 (fax)

Date:

August 19, 2011

Contact Person:

Gregory Neal
Regulatory Affairs Specialist II

(a)(2) Device Name

Proprietary Name:

PROFEMUR® E Cementless Hip Stem

Common Name:

Hip Stem

Classification Name and Reference:

21 CFR 888.3320 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis Class III

Subject Device Product Code and Panel Code:

Orthopedics/87/ JDL, KWA, LPH, LZO

(a)(3) Predicate Device

Predicate Proprietary Name:

STEM Hip Replacement System

Predicate Classification and Number:

888.3358 LPH Hip joint metal/polymer/ metal semi-constrained porous-coated uncemented prosthesis Class II **(510k-K021346)**

PRO-FEMUR Hip System
888.3353 LZO Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II **(510k-K012091)**

Metal TRANSCEND Articulation System
888.3320 JDL Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis Class III

888.3330 KWA Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis Class III **(510k-K004043)**

(a)(4) Device Description

The modular PROFEMUR® E Cementles Hip Stems hip stem is an uncemented distal femoral implant designed to couple with Wright Medical Technology's PROFEMUR® CoCr modular necks. The stem design was developed from the previously marketed PROFEMUR® Z Hip Stem ('STEM' K021346) and possesses the identical modular neck taper socket and is made of the identical Titanium alloy (ASTM F620) as previous hip stem designs by Wright.

(a)(5) Intended Use of the Device
Intended Use

The PROFEMUR® E Cementless Hip Stem is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The PROFEMUR® E Cementless Hip Stem is a single use component, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

(a)(6) Technological Characteristics of the Device
The indications for use for the PROFEMUR® E Cementless Hip Stem are identical to those for all existing Wright PROFEMUR® hip stems. The indications are applied to all PROFEMUR® hip stems and have been cleared in 510(k)s: K041114, K041586, K051995, K052915, K053588, K060358, K080663, K081090, K091423, and K100866.

The PROFEMUR® E Cementless Hip Stem is made of the same Titanium alloy and features a corundum blast surface finish similar to the PROFEMUR® Z Hip Stem (K021346). The PROFEMUR® E Cementless Hip Stem shares the rectangular cross-section of the predicate devices, and is designed to feature additional tapered lateral fins on each stem side.

(b)(1) Nonclinical Testing
The PROFEMUR® E Cementless Hip Stem represents a minor change to the PROFEMUR® Z Hip Stem (K021346). Proximal and distal fatigue, fretting, and distraction evaluations were conducted on the PROFEMUR® E Cementless Hip Stem. The results were similar to the PROFEMUR® Z Hip Stem (K021346).

(b)(2) Clinical Testing
Clinical data was not provided for the class III modular hip stem.

(b)(3) Conclusions
The indications for use of the PROFEMUR® E Cementless Hip Stem are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the subject device has not changed relative to the predicate devices. The safety and effectiveness of the PROFEMUR® E Cementless Hip Stem is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Mr. Gregory Neal
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

AUG 19 2011

Re: K111698
Trade/Device Name: PROFEMUR® E Cementless Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LPH, LZO
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Neal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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WRIGHT.

Indications for Use

Device Name: PROFEMUR® E Cementless Hip Stem

Indications For Use:

The PROFEMUR® E Cementless Hip Stem is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
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The PROFEMUR® E Cementless Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of an uncemented total hip arthroplasty.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111698